K121018 (1/3)

JUN 22 2012

510(k) Summary
Smith & Nephew, Inc. BIORAPTOR® 2.9, BIORAPTOR® PK 2.3, OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors

Submitted by:	Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810
Date of Summary:	April 3, 2012
Contact Person and Address:	John Connor, Regulatory Affairs Specialist T (901) 399-5944 F (901) 566-7961
Name of Device(s):	Smith & Nephew, Inc. BIORAPTOR® 2.9 Suture Anchor Smith & Nephew, Inc. BIORAPTOR® 2.3 PK Suture Anchor Smith & Nephew, Inc OSTEORAPTOR® Suture Anchor Smith & Nephew, Inc. BIORAPTOR® Knotless Suture Anchor
Common Name:	Fastener, Fixation, Biodegradable, Soft Tissue Fastener, Fixation, Nondegradable, Soft Tissue
Device Classification Name and Reference:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	MAI, MBI

Device Description
Subject of this Traditional 510(k) premarket notification is an addition to the indications for use for the Smith & Nephew, Inc. BIORAPTOR® 2.9, BIORAPTOR® 2.3 PK, OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors. These suture anchors were cleared via premarket notifications K053344, K071586, K082215, and K093428, respectively, and have identical indications for use. Smith & Nephew, Inc. seeks to expand the existing indications for use for the subject devices to include acetabular labrum reconstruction.

Technological Characteristics
There have been no major changes in design or materials in the subject suture anchors since their market clearance. As such, the technological characteristics of the BIORAPTOR® 2.9, BIORAPTOR® 2.3 PK OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors have not changed.

Intended Use

The Smith & Nephew, Inc. BIORAPTOR® 2.9, BIORAPTOR® 2.3 PK, OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors are intended for use in the attachment or reattachment of soft tissue to bone for the following indications:

Hip

Hip capsule repair (Acetabular labrum **reattachment/reconstruction**)

Shoulder

Capsular stabilization (Bankart repair, Anterior shoulder instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstructions), Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff tear repairs, Biceps tenodesis

Foot and Ankle

Hallux valgus repairs, Medial or lateral instability repairs/reconstructions, Achilles tendon repairs/reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repair/reconstructions, Bunionectomy

Elbow, Wrist, and Hand

Biceps tendon reattachment, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair

Knee

Extra-capsular repairs (Medial collateral ligament, Lateral collateral ligament, Posterior oblique ligament), Patellar realignment and tendon repairs (Vastus medialis obliquous advancement), Iliotibial band tenodesis

Substantial Equivalence Information

The substantial equivalence of the BIORAPTOR® 2.9, BIORAPTOR® 2.3 PK, OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors is based on similarities in indications for use, design features, operational principles, and material composition to the predicate devices listed in the table below. As there have been no significant changes to the design of the subject suture anchors, and the expansion of indications for use to include labral reconstruction introduces no additional risk, Smith & Nephew is relying on the mechanical testing (insertion strength, pull-out strength, and suture sliding) provided for the predicate devices as a measure of substantial equivalence.

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	BIORAPTOR® 2.9 Suture Anchors	K053344	02/23/2006
Smith & Nephew, Inc.	BIORAPTOR® 2.3 PK Suture Anchors	K071586	08/17/2007
Smith & Nephew, Inc.	OSTEORAPTOR® Suture Anchors	K082215	11/03/2008
Smith & Nephew, Inc.	BIORAPTOR® Knotless Suture Anchors	K093428	12/17/2009

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to expand the indications for use for the BIORAPTOR® 2.9, BIORAPTOR® 2.3 PK, OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors. Based on the similarities to the predicate components and published articles supporting the additional indication, the devices are substantially equivalent to their predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 22 2012

Smith and Nephew, Inc.
% Mr. John Connor
7135 Goodlett Farms Parkway
Cordova, Tennesee 38016

Re: K121018
Trade/Device Name: BIORAPTOR™ 2.9, BIORAPTOR™ 2.3 PK, OSTEORAPTOR™, and BIORAPTOR™ Knotless Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, MAI
Dated: April 3, 2012
Received: April 4, 2012

Dear Mr. Connor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K121018

Device Name: BIORAPTOR® 2.9, BIORAPTOR 2.3 PK, OSTEORAPTOR®, and BIORAPTOR® Knotless Suture Anchors

Indications for Use:
The Smith & Nephew Suture Anchors are intended for the reattachment of soft tissue to bone for the following indications:

Hip
Hip capsule repair
- Acetabular labrum reattachment/reconstruction

Shoulder
Capsular stabilization
- Bankart repair
- Anterior shoulder instability
- SLAP lesion repairs
- Capsular shift or capsulolabral reconstructions

Acromioclavicular separation repairs
Deltoid repairs
Rotator Cuff repairs
Biceps Tenodesis

Foot and Ankle
Hallux valgus repairs
Medial or lateral instability repairs/reconstructions
Achilles tendon repairs/reconstructions
Midfoot reconstructions
Metatarsal ligament/tendon repairs/reconstructions
Bunionectomy

Elbow, Wrist, and Hand
Biceps tendon reattachment
Ulnar or radial collateral ligament reconstructions
Lateral epicondylitis repair

Knee
Extra-capsular repairs
- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament

Patellar realignment and tendon repairs
- Vastus medialis obliquous advancement

Iliotibial band tenodesis

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121018

Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)